

**IN THE UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

**IN RE NATIONAL PRESCRIPTION  
OPIATE LITIGATION**

**MDL No. 2804  
Case No. 17-md-2804  
Judge Dan Aaron Polster**

**This document relates to:**

*The County of Cuyahoga v. Purdue  
Pharma L.P., et al.*, Case No. 17-OP-45004

*The County of Summit, Ohio, et al. v.  
Purdue Pharma L.P. et al.*,  
Case No. 18-OP-45090

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**MEMORANDUM IN SUPPORT OF DEFENDANTS'  
MOTION TO EXCLUDE DAVID EGILMAN'S  
OPINIONS AND PROPOSED TESTIMONY**

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## **I. INTRODUCTION.**

Dr. David Egilman compares the Defendants to the “mafia” and labels a former executive the “Pablo Escobar of the New Millennium.”<sup>1</sup> His report lists more than 500 unexplained and unsupported “opinions”—many of them one- or two-sentence statements—that range from his musings on the origins of the opioid abuse epidemic to musings that the Defendants formed a “Venture” that convinced the FDA to “Adopt Poor Epidemiological Practices To Approve Opioids. It Was Pay To Play And Probably Violated Anti-Trust Laws As Well.”<sup>2</sup> Egilman offers his personal judgment about the Defendants’ corporate knowledge, decisions, and intent. He applies arbitrary and personal ethical standards to second-guess and reach legal conclusions about the Defendants. Even a cursory review of his report reveals he has failed to use any expert methodology. Instead, he describes and interprets a selection of non-technical historical documents chosen not through a replicable or reliable methodology, but rather by running undisclosed search terms across the litigation database and cherry-picking results. He broadly uses the term “Venture” to suggest that a single Defendant’s conduct applies to *all* Defendants in this litigation without evidentiary support. Indeed, for the majority of his opinions, Egilman provides zero analysis. For his nearly 200 opinions offered against an all-encompassing “Venture,” there is no way to know how Egilman reached those conclusions, and no way for an individual Defendant to know whether the opinion applies to it or not. Even a superficial review of Egilman’s report and deposition testimony reveals that Plaintiffs intend for him to serve as a mouthpiece who will do nothing more than introduce and provide his subjective interpretation of documents, even though they are within the jury’s competence and sole responsibility to evaluate.

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<sup>1</sup> Ex. 1, Egilman Rpt. ¶¶ 7.228, 7.196.

<sup>2</sup> *Id.*, ¶ 7.103.

Egilman does not offer an *expert* opinion. Instead, he is a zealous and partisan crusader. Yet Plaintiffs expect this Court to cloak Egilman in the garb of “expert” so he can offer an improper and prejudicial closing argument from the witness box. The Federal Rules of Evidence and *Daubert* demand more. True expert witnesses offer specialized knowledge or expertise to help the jury resolve fact disputes. Egilman’s opinions do not meet that standard, so the Court should exclude his testimony.

Not surprisingly, courts have excluded Egilman’s opinions because they were simply his subjective beliefs unsupported by any reliable methodology. Most notably, one federal court excluded his opinions as unsupported speculation or improper legal conclusions. *Newkirk v. ConAgra Foods, Inc.*, 727 F. Supp. 2d 1006, 1022, 1026, 1029 (E.D. Wash. 2010).<sup>3</sup> Other courts held Egilman’s opinions were conclusory, *Freels v. U.S. R.R. Ret. Bd.*, 879 F.2d 335, 343 (8th Cir. 1989), unsupported by reliable methodology or evidence, *Lane v. Gasket Holdings, Inc.*, No. B153966, 2003 WL 21666623, at \*6–7 (Cal. App. Jul. 17, 2003), or based on a false assumption. *Merck & Co., Inc. v. Ernst*, 296 S.W.3d 81, 96 (Tex. App. 2009).

More troubling, Egilman is willing to violate court orders when it suits his purposes. In the *Zyprexa* litigation, Egilman violated a protective order and leaked the defendant’s confidential documents to the *New York Times*. Faced with potential criminal and civil sanctions, he paid \$100,000 (which the defendant donated to charity). He also admitted that he “released a set of documents that did not represent the entire set of information concerning [defendant]’s action and knowledge” and that he did not “get [defendant]’s perspective on the

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<sup>3</sup> After the Ninth Circuit affirmed his exclusion, 438 F. App’x 607, 609 (9th Cir. 2011), Egilman *personally* filed a writ of certiorari seeking review of the decision (which the Supreme Court denied). 568 U.S. 1229 (Mem) (Mar. 18, 2013).

side effects publicized to doctors or patients.”<sup>4</sup> And this was not the first time. Six years earlier, a Colorado court questioned Egilman’s “legitimacy and integrity as a witness,” and struck his testimony after he “flagrant[ly]” violated a protective order and posted “scurrilous and inflammatory statements” on his web-site, noting that Egilman “was neither objective nor reliable” and that his conduct would “place at risk the fairness of the trial.”<sup>5</sup>

Any trial in this litigation will be widely scrutinized. It is important to the parties and the general public. If Egilman is permitted to testify, the risk of mistrial is great, even apart from Egilman’s track record and his open hostility to the Defendants and their lawyers. If Egilman is qualified by this Court to give what will amount to a closing argument and to serve as a document delivery vehicle, no amount of cross-examination will be sufficient to un-ring the bell and cure the prejudice of his improper, inadmissible, and outrageous opinions.

## **II. BACKGROUND.**

Egilman is an internist and doctor of preventive occupational medicine.<sup>6</sup> He has essentially stopped practicing medicine to work as a full-time advocate, and he has made millions as a highly paid expert witness for plaintiffs.<sup>7</sup> He lacks expertise in several of the subjects on which he purports to offer expert testimony, including: pharmaceutical labeling and regulatory approval, suspicious order monitoring, diversion prevention, and pharmaceutical distribution.<sup>8</sup>

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<sup>4</sup> Ex. 2, *In re Zyprexa Prods. Liab. Litig.*, MDL No. 1596, Stipulated Order and Declaration of David Egilman (Sept. 7, 2007); *see also Eli Lilly & Co. v. Gottstein*, 617 F.3d 186 (2d Cir. 2010) (detailing Egilman’s egregious conduct in the Zyprexa litigation).

<sup>5</sup> Ex. 3, *Ballinger v. Brush Wellman, Inc.*, No. 96-CV-2532, Findings, Conclusions and Orders Concerning Sanctions (Colo. Dist. Ct. June 22, 2001); *see also Egilman v. Keller & Heckman, LLP.*, 401 F. Supp. 2d 105 (D.D.C. 2005) (dismissing Egilman’s personal lawsuit against Jones Day).

<sup>6</sup> Egilman Dep., 117:22–118:17.

<sup>7</sup> *Id.* at 58:18–59:17, 60:02–13, 71:11–15, 203:03–21, 206:07–19.

<sup>8</sup> Egilman believes himself to be an expert in (without limitation): occupational environmental medicine, toxicology, molecular biology, warnings and risk communication, “[a]ll aspects of public health,” epistemology, sociology, anthropology, medical marketing, the side effects of pain medications, using “secret corporate documents and data,” international health, minority recruitment to medical schools, the rules and regulations of non-profit organizations,



Plaintiffs designated Egilman as a “catch-all” expert. He reviewed documents of his own choosing, “interpreted” those documents to align with his own biased and subjective view of Defendants’ motives, held Defendants’ conduct to legal and ethical standards of his own choosing, and offered conclusions on ultimate issues of the case. Egilman’s sprawling opinions include the following:

- Defendants acted in concert to corrupt the FDA;<sup>9</sup>
- Defendants hid their funding of research by laundering money through third parties;<sup>10</sup>
- Defendants “cooked the books”;<sup>11</sup>
- Defendants’ suspicious order monitoring was “a joke.”<sup>12</sup>

Egilman claims to have considered *all* of the documents produced by nearly *every* defendant in this MDL—hundreds of millions of pages—even though Plaintiffs retained him just seven months ago.<sup>13</sup> Yet Egilman’s report does not reflect a substantive review of the record in this case, or a methodology explaining how he formulated his opinions based on that record. Rather, more than 80 percent of Egilman’s opinions, including those attributable to the all-encompassing “Venture,” cite only a handful of documents, with no explanation, and with no indication that he attempted to review the record for documents contrary to his subjective interpretations and conclusions.<sup>14</sup>

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FDA regulations, suspicious order monitoring, addiction, the drug approval process, and the law. Egilman Dep., 102:09–115:17, 468:24–469:15, 476:13–478:02, 497:14–500:16, 507:16–509:18, 527:03–13; *see also id.* at 102:24–103:10 (Egilman’s flawed definition of an “expert”). In reality, Egilman is not an expert in any of these areas.

<sup>9</sup> Egilman Rpt. ¶ 7.69.

<sup>10</sup> *Id.* ¶ 7.80.

<sup>11</sup> *Id.* ¶ 7.339.

<sup>12</sup> *Id.* ¶ 7.461.

<sup>13</sup> Egilman Dep., 22:13–17, 138:23–139:15, 265:12–22.

<sup>14</sup> *E.g., id.* at 329:20–332:19, 330:17–342:07, 700:22–702:12.

**III. EGILMAN DID NOT USE A RELIABLE OR REPLICABLE METHODOLOGY AND DID NOT RELIABLY APPLY IT TO HIS OPINIONS.**

Egilman identified two approaches he allegedly used to form his opinions: (1) a “grounded theory approach,” and (2) evidence-based medicine methods. But Egilman cannot explain the particular mechanics of either technique. There is no way to know the method (if any) Egilman used for each opinion, or how he applied those methods to the opinions (if he did), so his process cannot be repeated.<sup>15</sup> At bottom, Egilman’s “methodology” is nothing more than an improper exercise in cherry-picking documents to support his pre-conceived conclusions.

The “grounded theory approach” means that Egilman merely used search terms to search through millions of documents, and arbitrarily changed those terms throughout the process as he saw fit.<sup>16</sup> He did not list the search terms used because it apparently is “an iterative process” where “[y]ou find something, then you pursue other things related to what you found.”<sup>17</sup> Egilman concedes there is no way to recreate his iterative process because “[i]t’s never going to be the same.”<sup>18</sup> Only Egilman knows what documents he decided to look for and what he opted to ignore.<sup>19</sup> Because this methodology resides strictly in Egilman’s mind, there is no way to test or replicate it; consequently, his opinions do not satisfy *Daubert*. See, e.g., *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000) (excluding expert testimony where an expert’s laboratory experiments could not be replicated). And while Egilman devotes eleven pages of his report to describing his alleged “evidence-based medicine method,” he admits that many of the steps he lists do not apply here.<sup>20</sup>

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<sup>15</sup> *Id.* at 150:08–16, 154:16–19, 231:06–12.

<sup>16</sup> *Id.* at 138:23–139:15, 173:16–174:13.

<sup>17</sup> *Id.* at 174:04–11.

<sup>18</sup> *Id.* at 323:17–324:2.

<sup>19</sup> *Id.* at 176:08–18, 250:01–07.

<sup>20</sup> Egilman Dep., 219:22–222:7, 224:2–12.

Egilman also failed to apply his unreliable methods to the facts of the case, as required by Rule 702. Egilman did the exact opposite: he came to his conclusions first, and then selectively picked “the best evidence [he] could find that supported the opinion” he had already formed.<sup>21</sup> This is “the antithesis of” a scientific method. *Claar v. Burlington N. R.R. Co.*, 29 F.3d 499, 502-03 (9th Cir. 1994). Egilman’s “methodology” of cherry-picking documents is an approach that federal courts of appeals have rebuked as “[r]esult-drive analysis” that “undermines principles of the scientific method” by “applying methodologies (valid or otherwise) in an unreliable fashion.” *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig.*, 892 F.3d 624, 634 (4th Cir. 2018); *see also In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 858 F.3d 787, 796 (3d Cir. 2017) (rejecting such opaque and selective methods as “a mere conclusion-oriented selection process”). Such testimony is “consistently excluded,” and should be here too. *EEOC v. Freeman*, 778 F.3d 463, 469 (4th Cir. 2015) (collecting cases).

#### **IV. EGILMAN OFFERS NOTHING MORE THAN SUBJECTIVE OPINIONS AND UNSUPPORTED SPECULATION.**

Egilman’s “opinions” lack support. A court should not admit expert testimony “that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.” *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 254 (6th Cir. 2001); *see also Numatics, Inc. v. Balluff, Inc.*, 66 F. Supp. 3d 934, 941–42 (E.D. Mich. 2014) (excluding expert testimony where, among other things, the expert relied on counsel for analysis and did not “tether his factual experience to his opinions”). Egilman’s expert report essentially amounts to a list of hundreds of statements based on his “interpretation” of hand-selected documents, regardless of whether he has any true expertise in the subject matter. For some, he relies on a single document without any analysis to

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<sup>21</sup> *Id.* at 818:10–17.

determine whether he understands the document at all or is taking it out of context.<sup>22</sup> Because the limited sources he actually cites do not support his broad opinions, Egilman resorts to speculation and extrapolation. This is a “[r]ed flag that caution[s] against certifying” Egilman as an expert. *Newell Rubbermaid, Inc. v. Raymond Corp.*, 676 F.3d 521, 527 (6th Cir. 2012).

For example, Egilman believes *all* Defendants “used the revolving door FDA-industry to get favorable rulings to enable them to expand the market to patients who they and the FDA knew were inappropriate for long term narcotics.”<sup>23</sup> In other words, Egilman believes the Defendants and the FDA worked together to deceive the public-health community and patients. Putting aside this baseless conspiracy theory, many of the Defendants in this case do not even market opioids, and Plaintiffs have not alleged marketing claims against them. Yet Egilman nonetheless leaps to the conclusion that “each and every one of [his] opinions that is cited for the Venture applies to each and every defendant in the opiate MDL.”<sup>24</sup> These same methodology concerns infect Egilman’s entire report, particularly regarding his far-reaching opinions on the “Venture.”<sup>25</sup>

Just as in *Newkirk v. ConAgra Foods Inc.*, where the Ninth Circuit affirmed the exclusion of Egilman’s testimony, his opinions here “do not rise above subjective belief or unsupported speculation,” and he “fails to apply reliable scientific methods when he extrapolates from

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<sup>22</sup> *E.g.*, Egilman Dep., 277:01–280:11 (discussing ¶ 7.100); *id.* at 287:02–291:14 (discussing ¶ 7.21); *id.* at 651:17–652:02 (discussing ¶ 7.136); *id.* at 731:16–732:22 (discussing ¶ 7.56); *id.* at 776:20–778:21 (discussing ¶ 7.487); *id.* at 788:20–790:03 (discussing ¶ 7.480).

<sup>23</sup> Egilman Rpt. ¶ 7.71.

<sup>24</sup> Egilman Dep., 325:02–09.

<sup>25</sup> *E.g.*, *id.* at 329:20–332:19 (admitting that the only basis cited for his opinion, “The ‘Venture’ should have known that higher doses kill and warned about this,” is a screenshot of the first page of an article); *id.* at 338:17–345:14 (admitting that the only basis cited for his opinion, “had any ‘Venture’ member broken ranks, the opioid market would have slowed or if the complete truth was told (no efficacy and high addiction risk) the market would have crashed,” is a screenshot of a Janssen document that says nothing about breaking ranks); *id.* at 345:15–349:19 (admitting that the only basis cited for his opinion, “When the FDA tried to limit use in 2001 by changing the label from ‘more than a few days’ to ‘extended period of time,’ the ‘Venture’ used this language to increase the market,” is a quotation from a CBS news article and an email from Purdue).

extremely small samplings to make sweeping conclusions.” 727 F. Supp. 2d at 1022, 1029. Thus, the Court should exclude all of Egilman’s opinions as unreliable.

**V. EGILMAN’S FAILURE TO APPLY ANY RELIABLE METHODOLOGY OR EXPERTISE RESULTS IN OPINIONS THAT ARE IMPROPER AND INADMISSIBLE.**

Egilman offers impermissible legal opinions designed to usurp the jury’s role as the fact-finder. He fails to apply any expertise to his opinions and instead purports to interpret cherry-picked documents that the jurors can interpret for themselves following presentation of evidence and attorney argument. The Court should not allow this testimony. “An expert witness should never become one party’s expert advocate.” *Selvidge v. United States*, 160 F.R.D. 153, 156 (D. Kan. 1995). Courts consistently reject expert opinions “that are, in substance, the arguments of counsel.” *Raley v. Hyundai Motor Co.*, No. 08-0376-HE, 2010 WL 199976, at \*4 (W.D. Okla. Jan. 14, 2010); *see, e.g., Occulto v. Adamar of N.J., Inc.*, 125 F.R.D. 611, 616 (D.N.J. 1989) (expert may not “participate as the alter-ego of the attorney who will be trying the case”).

**A. Egilman May Not Testify About Defendants’ Corporate Conduct.**

In a situation strikingly similar to the one here, the plaintiffs’ counsel in the *Rezulin* litigation—including some of the same counsel involved in this MDL—offered several experts “whose intended role [was] more to argue the client’s cause from the witness stand than to bring to the fact-finder specialized knowledge or expertise that would be helpful in resolving issues of fact presented by the lawsuit.” *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 538 (S.D.N.Y. 2004). Like Egilman, the experts in that case opined about “what constitutes ethical behavior for a company,” “the motive, intent, and state of mind of” corporate defendants, and a corporate defendant’s “duty to warn patients” and “alleged failure to provide adequate information to the FDA.” *Id.* at 539. The court considered whether the proffered opinions “usurp either the role of the trial judge in instructing the jury as to the applicable law or the role

of the jury in applying that law to the facts before it.” *Id.* at 541 (quotations omitted). Applying that standard, the court barred testimony on a variety of topics, including: historical narrative and commentary; corporate ethics; corporate motives, intent, and state of mind; and regulatory disclosures. Specifically, the court excluded the opinions of one expert who offered “a narrative of the case which a juror is equally capable of constructing.” *Id.* at 551. The court cautioned, “the glosses that [the expert] interpolates into his narrative are simple inferences drawn from uncomplicated facts that serve only to buttress plaintiffs’ theory of the case.” *Id.*

This Court has previously precluded expert testimony about the alleged knowledge, motivations, intent or purposes of corporate defendant, its employees, and the FDA. *In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*, MDL No. 1909, 2010 WL 1796334, at \*12-13 (N.D. Ohio May 4, 2010) (Polster, J.). In another case involving a prescription medication, the court precluded an expert from testifying about “the content or significance of certain [] corporate documents” when offered as evidence of corporate intent. *Bouchard v. Am. Home Prods. Corp.*, No. 3:98-cv-7541, 2002 WL 32597992, at \*6 (N.D. Ohio May 24, 2002). As another court recently reaffirmed:

Expert testimony ... as to intent, motive, or state of mind offers no more than the drawing of an inference from the facts of the case. The jury is sufficiently capable of drawing its own inferences regarding intent, motive, or state of mind from the evidence, and permitting expert testimony on this subject would be merely substituting the expert’s judgment for the jury’s and would not be helpful to the jury.

*Lucio v. Levy Envtl. Serv. Co.*, 173 F. Supp. 3d 558, 565 (N.D. Ohio Mar. 22, 2016).

Egilman’s opinions are inadmissible for the same reasons. He selected and “interpreted” a collection of documents—most over a decade old and selected by a subjective methodology Egilman could not properly explain and cannot be repeated—to support a pre-determined and biased story about the Defendants. Those same documents, if relevant and admissible, could be

examined and readily understood by a jury; indeed, these are “lay matters which a jury is capable of understanding and deciding without the expert’s help.” *In re Rezulin*, 309 F. Supp. 2d at 546; *see also CMI-Trading v. Quantum Air*, 98 F.3d 887, 890 (6th Cir. 1996) (expert’s personal opinion of parties’ intent invaded province of jury); *Wells v. Allergan, Inc.*, No. 12-973-C, 2013 WL 7208221, at \*2 (W.D. Okla. Feb. 4, 2013) (improper for expert to “simply rehash otherwise admissible evidence about which he has no personal knowledge,” “construct[] a factual narrative based upon record evidence,” and “address lay matters which [the factfinder] is capable of understanding and deciding without the expert’s help”) (citations and quotations omitted).

Even if this were a permissible topic of opinion (and it is not), Egilman is unqualified to provide it because he has no specialized expertise in corporate conduct. It is well-established that an expert witness may not testify on matters outside his field of expertise. *See Smelser v. Norfolk S. Ry. Co.*, 105 F.3d 299, 301 (6th Cir. 1997), *abrogated on other grounds by Morales v. Am. Honda Motor Co.*, 151 F.3d 500 (6th Cir. 1998). It is not enough that Egilman is a medical doctor and professor of community medicine. *Cf. In re Commercial Money Ctr., Inc.*, 737 F. Supp. 2d 815, 844 (N.D. Ohio 2010) (excluding testimony where “vast portions” of expert’s report “go far beyond his experience” and “many of which are outside the area of proper expert testimony”). Egilman has never worked for a pharmaceutical company and has no specialized expertise in pharmaceutical corporate conduct.<sup>26</sup>

In the *Diet Drug* litigation, the court did not allow science experts to testify about corporate intent:

The witnesses are qualified in particular scientific disciplines. ***These disciplines do not include knowledge or even experience in the manner in which corporations and the pharmaceutical marketplace react, behave or think*** regarding their nonscientific goals of maintaining a profit-making organization that is subject to

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<sup>26</sup> Egilman Dep., 515:14–16.

rules, regulations, standards, customs and practices among competitors and influenced by shareholders or public opinion.

*In re Diet Drugs Prods. Liab. Litig.*, MDL No. 1203, 2000 WL 876900, at \*9 (E.D. Pa. June 20, 2000) (emphasis added). The *In re Rezulin* court reached the same conclusion where “opinions of these witnesses on the intent, motives or states of mind of corporations . . . have no basis in any relevant body of knowledge or expertise.” 309 F. Supp. 2d at 546. And the same is true of Egilman’s opinions.

B. **Egilman May Not Offer Opinions About The Adequacy Of Defendants’ Warnings, Labeling, Or Suspicious Order Monitoring Programs.**

For similar reasons, Egilman is unqualified to opine on the adequacy of Defendants’ warnings or suspicious order monitoring programs. Expertise in one area does not qualify any witness as an expert in other—even related—areas. “The issue with regard to expert testimony is not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question.” *Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994).

In *Rheinfrank*, the Sixth Circuit affirmed the exclusion of testimony from a neurologist, geneticist, and epidemiologist—all of whom were unqualified to opine on regulatory issues—because they lacked the specialized training or professional experience about medication-labeling requirements. *Rheinfrank v. Abbott Labs., Inc.*, 680 F. App’x 369, 380 (6th Cir. 2017). See also *In re Heparin Prod. Liab. Litig.*, MDL No. 1953, 2011 WL 1059660, at \*10-11 (N.D. Ohio Mar. 21, 2011) (expert not qualified to offer opinions concerning pharmaceutical drug or API manufacturing, testing, and quality control where he had no knowledge of FDA regulations or drug safety standards, had never been hired by a pharmaceutical company, and had no first-hand experience with the pharmaceutical industry outside of litigation); *Brown v. Roche Lab., Inc.*, No. 1:06-cv-3074-JEC, 2013 WL 2457950, at \*3–4 (N.D. Ga. June 6, 2013), *aff’d on other*



*grounds*, 567 F. App'x 860 (11th Cir. 2014); *In re Trasyol Prod. Liab. Litig.*, MDL No. 1928, 2011 WL 7109297, at \*6–7 (S.D. Fla. Apr. 27, 2011).

This is exactly what Egilman wants to offer here: for example, what “should have” been in the package inserts for Manufacturers’ prescription opioid products.<sup>27</sup> Egilman has no relevant experience—and therefore no “specialized knowledge,” as required by Rule 702—about the development and modification of prescription medication labeling, the FDA’s enforcement of its labeling regulations, or the regulation of prescription-medication promotion. It does not matter that Egilman has taught and written on the general subject of warnings.<sup>28</sup> He admits he has never “worked on a new drug application with the FDA,” has never “worked with the FDA on any drug approval,” has never “reviewed a new drug application” for the FDA, has never “been involved in submitting an NDA,” has never worked for DDMAC or the Office of Prescription Drug Promotion, has never “worked for or consulted with the Federal Trade Commission,” and has never “been employed by a pharmaceutical company.”<sup>29</sup>

Similarly, Egilman has no specialized knowledge or relevant experience about the development and operation of SOM systems, a corporation’s compliance with SOM requirements, or the DEA’s enforcement of SOM or other anti-diversion regulations. He in fact has no personal experience with the DEA, has never consulted for the DEA, and has never previously offered an expert opinion on SOM compliance.<sup>30</sup> He has never worked for any entity to review their standard SOM practices, has never developed a SOM system or interpreted SOM regulations, and is not familiar with algorithms used to detect suspicious orders.<sup>31</sup> Because he is

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<sup>27</sup> See, e.g., Egilman Rpt. ¶¶ 7.38, 7.419, 7.455.

<sup>28</sup> See *id.* at Sec. 2, pp. 31–33.

<sup>29</sup> Egilman Dep., 510:14–511:3, 514:7–11, 515:11–16, 518:5–10.

<sup>30</sup> *Id.* at 471:03–11, 474:15–17, 477:03–8.

<sup>31</sup> *Id.* at 474:18–475:06, 474:02–05.

unqualified, Egilman should be precluded from testifying about the Defendants' warnings, labeling, or suspicious order monitoring.

C. **Egilman May Not Testify That Defendants Violated Ethical Or Legal Obligations.**

Egilman proposes to testify that Defendants did not comply with their ethical or legal obligations—as defined by him—in a number of ways, including: that Defendants “should have” trained doctors on “proper[]” opioid disposal;<sup>32</sup> that Defendants both had and violated a duty to doctors to ensure they received “FDA-mandated warning labels in the Physician’s Desk Reference (PDR) for all of their drugs they sold for every year that they were sold”;<sup>33</sup> and that Defendants “destroyed documents.”<sup>34</sup> Whether characterized as legal obligations, moral duties, or both, these are not the proper subject of expert opinion testimony. It will be for this Court to instruct the jury on the requirements of the relevant law, and then for the jury to apply that law to the facts and evidence before it. Expert testimony couched in terms of a “legal conclusion” is “not helpful to the jury.” *Torres v. Cnty. of Oakland*, 758 F.2d 147, 150 (6th Cir. 1985). Here, Egilman’s unsupported opinions are nothing more than improper legal conclusions that are “at best, unhelpful to the jury” and, “[a]t worst,” “confusing and extremely misleading.” *In re Commercial Money Ctr, Inc.*, 737 F. Supp. 2d at 844 (excluding expert testimony where the expert report was “riddled with vague and unsupported statements, many of which are outside the area of proper expert testimony and many of which are blatantly improper legal conclusions”).

Egilman’s opinions about supposed ethical or moral obligations also are improper. Expert testimony must help the jury decide an issue that is actually before it. *Daubert v. Merrell*

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<sup>32</sup> Egilman Rpt. ¶ 7.419.

<sup>33</sup> *Id.* ¶ 7.386

<sup>34</sup> *Id.* ¶ 7.162

*Dow Pharm., Inc.*, 509 U.S. 579, 590–91 (1993). Here, there is no connection between Egilman’s theory of what constitutes a “moral” corporation and the issue the jury must decide—whether Defendants’ conduct comports with Defendants’ *legal* obligations. Testimony about the former will do nothing to advance fact finding on the latter. In the *Welding Fume* litigation, the court excluded similar proffered testimony “about business ethics generally and also whether the defendants acted ethically.” *In re Welding Fume Prods. Liab. Litig.*, MDL No. 1535, 2010 WL 7699456, at \*24 (N.D. Ohio June 4, 2010). The court explained:

Every one of [the expert’s] seven ethical standards is precatory - each sets out what a corporation *should* do. No right-minded person would disagree with the aspirational character of [the expert’s] ethical principles. But the critical question for a *Welding Fume* jury is whether the defendant corporations did what the law *required* them to do, not whether, from a societal perspective, they did what an “ethical corporation” *should have* done. [The expert’s] opinions regarding the latter, accordingly, would tend to misdirect the finder of fact.

*Id.* (emphasis in original).

Egilman’s opinions about ethical obligations likewise would confuse the jury and cause it to believe it could determine liability regardless of applicable legal standards. His testimony would “unfairly [] prejudice and confuse the trier by introducing the experts’ opinions and rhetoric concerning ethics as alternative and improper grounds for decision on bases other than the pertinent legal standards.” *In re Rezulin*, 309 F. Supp. 2d at 545. Egilman’s confusing and misleading testimony should be excluded.

## **VI. EGILMAN’S OPINIONS ARE UNFAIRLY PREJUDICIAL.**

Egilman, with the help of Plaintiffs’ counsel and his own say-so, describes *all* Defendants as a “Venture,” and repeatedly accuses them of “acting in a concerted fashion.”<sup>35</sup> Egilman’s use

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<sup>35</sup> Egilman Rpt. at Sec. 4.4 & ¶¶ 7.7, 7.18, 7.68, 7.158, 7.270, 7.299, 7.337, 7.369, 7.404, 7.431, 7.447, 7.473, 7.488; *see also* Egilman Dep., 81:07–12, 291:23–293:03, 302:18–303:05.

of legal terms of art is intentional: he seeks to imply criminal intent and wrongdoing on the part of Defendants.<sup>36</sup> Even if Egilman does not intend to refer to these terms in the legal sense, there is a material risk that a jury would not appreciate the distinction.<sup>37</sup> See *Scanlan v. Sunbeam Prod., Inc.*, No. 3:12-CV-9-S, 2015 WL 10711206, at \*6 (W.D. Ky. Sept. 1, 2015) (excluding expert testimony where expert’s use of the word “neglect” was “deeply concern[ing]” given “the highly connotative nature of the term, which has distinct criminal overtones”). Egilman’s opinions create a danger of unfair prejudice and confusion, and therefore should be excluded.

Egilman compares the Defendants to the mafia and describes the former Co-chairman and President of Purdue Pharma as “the Pablo Escobar of the New Millennium.”<sup>38</sup> These statements must be seen for what they are—a blatant attempt to inflame and prejudice the jury against Defendants. Because “[e]xpert evidence can be both powerful and quite misleading,” under Rule 403 the court “exercises more control over experts than over lay witnesses.” *Daubert*, 509 U.S. at 595 (citation omitted). Rule 403 bars these irrelevant, sensational, and inflammatory opinions.

## **VII. CONCLUSION**

If Egilman is permitted to testify, the risk of mistrial is great, as no amount of cross-examination will be sufficient to cure the prejudice of his improper, inadmissible, and outrageous opinions. This Court should exclude his testimony in its entirety.

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<sup>36</sup> *E.g.*, Egilman Dep., 325:02–327:11, 738:20–739:08 (comparing the “Venture” to a bank robbery in that “they’re all participants” and “all 100 percent responsible” for “destroying these communities,”); *id.* at 613:10–18 (opining “only objective” of the “Venture” was to “[m]ake as much money as possible”).

<sup>37</sup> *Id.* at 680:20–681:15.

<sup>38</sup> Egilman Rpt. ¶¶ 7.228, 7.196.

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**CERTIFICATE OF SERVICE**

I, Will Sachse, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record.

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